

**FLORENCE CRAMER,**

**Plaintiff,**

**vs.**

**ETHICON, INC., ET AL.,**

**Defendants.**

**THIS MATTER** comes before the Court on a Motion to Dismiss the Original Complaint, filed by Defendants Ethicon, Inc. and Johnson & Johnson, (Doc. No. 8), and on a Motion to Dismiss the Amended Complaint, filed by Defendants Ethicon, Inc. and Johnson & Johnson, (Doc. No. 14).

Plaintiff Florence Cramer brings a product liability action against Defendants Ethicon, Inc. and Johnson & Johnson (collectively, “Defendants” or “Ethicon”). Plaintiff’s Amended Complaint alleges that she has suffered damages as a result of having been implanted on April 2, 2007, with Ethicon, Inc.’s TVT-O prescription pelvic mesh medical device to treat her urinary incontinence. Specifically, Plaintiff asserts the following causes of action: failure to warn (Count I), negligence (Count II), design defect (Count III), manufacturing defect (Count IV), breach of implied warranty (Count V), violation of North Carolina Consumer Protection and Deceptive Business Practices Act (Count VI), and punitive damages (Count VII).

Case 1:20-cv-00095-MOC-WCM Document 21 Filed 01/25/21 Page 1 of 12

April 2, 2007, Plaintiff underwent surgery to have Ethicon, Inc.'s TVT-O implanted at Margaret R. Pardee Memorial Hospital in Hendersonville, North Carolina. On April 25, 2017, Plaintiff underwent a surgical revision of the TVT-O at Park Ridge Health in Hendersonville, North Carolina. Plaintiff alleges that her TVT-O implant has caused her to suffer physical, mental, financial, and/or economic injury and/or loss.

On April 20, 2020, Plaintiff filed this product liability action, asserting claims for failure to warn (Count I), negligence (Count II), negligent misrepresentation (Count III), design defect (Count IV), manufacturing defect (Count V), breach of express warranty (Count VI), breach of implied warranty (Count VII), violation of North Carolina Consumer Protection and Deceptive Business Practices Act (Count VIII), fraud (Count IX), fraud by concealment (Count X), and punitive damages (Count XI).

On July 20, 2020, Defendants moved to dismiss Plaintiff's Complaint on the ground that her claims were barred by the statute of repose. (Doc. No. 8). On August 21, 2020, this Court issued an Order granting Plaintiff leave to amend her Complaint to add allegations relating to the application of the statute of repose. (Doc. No. 12). On September 10, 2020, Plaintiff filed her Amended Complaint, asserting claims for failure to warn (Count I), negligence (Count II), design defect (Count III), manufacturing defect (Count IV), breach of implied warranty (Count V), violation of the North Carolina Consumer Protection and Deceptive Business Practices Act (Count VI), and punitive damages (Count VII). (Doc. No. 13). The Amended Complaint abandoned the claims for negligent misrepresentation, breach of express warranty, fraud, and fraud by concealment that Plaintiff had asserted in her original Complaint.

With respect to the statute of repose issue, Plaintiff added two new factual allegations to the Amended Complaint: (1) that "[b]etween 2011 and 2017, Plaintiff suffered from persistent

and/or chronic urinary tract and bladder infections, but did not associate these problems with Defendants' Pelvic Mesh product," and (2) that "Plaintiff did not know until 2017 that her chronic urinary tract and bladder infections were caused by Defendants' Pelvic Mesh product." (*Id.* at ¶¶ 23, 24).

Defendants filed their second motion to dismiss on September 24, 2020. Defendants move for dismissal of Plaintiff's Amended Complaint as barred by North Carolina's statute of repose for product liability actions. Defendants contend that, regardless of whether the Court applies the six-year statute of repose in effect at the time of Plaintiff's implant or the twelve-year statute of repose adopted in 2009, it is undisputed that Plaintiff did not file this action until more than 13 years after her TVT-O implant. Defendants further contend that the "disease exception" to the statute of repose does not apply in this case because Plaintiff has not alleged that she was diagnosed with any disease as a result of her implant. Alternatively, Defendants request that this Court dismiss Plaintiff's claims for manufacturing defect and breach of implied warranty as insufficiently pleaded or otherwise precluded as a matter of law. Plaintiff filed a response on October 8, 2020. On October 13, 2020, Defendant informed the Court that it did not intend to file a Reply. Thus, this matter is ripe for disposition.

## **II. STANDARD OF REVIEW**

Federal Rule of Civil Procedure 12(b)(6) provides that a motion may be dismissed for failure to state a claim upon which relief can be granted. A motion to dismiss pursuant to Rule 12(b)(6) tests the sufficiency of the complaint without resolving contests of fact or the merits of a claim. *Republican Party of N.C. v. Martin*, 980 F.2d 943, 952 (4th Cir. 1992), *cert. denied*, 510 U.S. 828 (1993). Thus, the Rule 12(b)(6) inquiry is limited to determining if the allegations constitute "a short and plain statement of the claim showing the pleader is entitled to relief"

pursuant to Federal Rule of Civil Procedure 8(a)(2). To survive a defendant’s motion to dismiss, factual allegations in the complaint must be sufficient to “raise a right to relief above a speculative level.” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). Thus, a complaint will survive if it contains “enough facts to state a claim to relief that is plausible on its face.” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Twombly, 550 U.S. at 570).

For the purposes of a Rule 12(b)(6) analysis, a claim has facial plausibility “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Id. (quoting Twombly, 550 U.S. at 556). The Court must draw all reasonable factual inferences in favor of the plaintiff. Priority Auto Grp., Inc. v. Ford Motor Co., 757 F.3d 137, 139 (4th Cir. 2014). In a Rule 12(b)(6) analysis, the Court must separate facts from legal conclusions, as mere conclusions are not entitled to a presumption of truth. Iqbal, 556 U.S. at 678. Importantly, “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” Id. However, well-pleaded factual allegations are entitled to a presumption of truth, and the court should determine whether the allegations plausibly give rise to an entitlement to relief. Id. at 679.

### **III. DISCUSSION**

#### **A. Applicable State Law**

When, as here, a federal court sits in diversity, it applies the choice of law rules of the forum state. Klaxon Co. v. Stentor Elec. Mfg. Co., 313 U.S. 487, 496 (1941). North Carolina courts use two different choice-of-law approaches, both of which support the application of North Carolina substantive law to Plaintiff’s claims in this case. For tort claims, North Carolina applies the “lex loci delicti” approach. Harco Nat’l Ins. Co. v. Grant Thornton LLP, 698 S.E.2d 719, 722–23 (N.C. App. 2010).

This approach provides that “the state where the injury occurred is considered the situs of the claim.” Id. at 722 (quoting Boudreau v. Baughman, 368 S.E.2d 849, 853–54 (N.C. 1988)). The alleged injury for a prescription medical device occurs in the state of the implant. See Simmons v. Boston Sci. Corp., No. 2:12-cv-07398, 2015 WL 2137145, at \*2–3 (S.D. W. Va. May 7, 2015). For warranty claims, North Carolina applies the “most significant relationship” approach, which “requires the forum to determine which state has the most significant relationship to the case.” 698 S.E.2d at 723. North Carolina courts have found that “the place of sale, distribution, delivery, and use of the product, as well as the place of the injury—to be the state with the most significant relationship to the warranty claims.” Boudreau, 368 S.E.2d at 855–56.

Here, Plaintiff is seeking damages for alleged injuries that occurred in North Carolina, where Plaintiff was implanted with the allegedly defective device. In addition, Plaintiff is a resident citizen of North Carolina, and all relevant medical care and treatment took place in North Carolina. As such, North Carolina is the place of the alleged injury and the state with the most significant relationship to Plaintiff’s claims. Accordingly, North Carolina substantive law applies to Plaintiff’s claims.

#### **B. North Carolina Statute of Repose**

North Carolina has a statute of repose for all “action[s] for the recovery of damages for personal injury, death, or damage to property based upon or arising out of any alleged defect or any failure in relation to a product.” N.C. GEN. STAT. § 1-46.1(1). All product liability claims, regardless of their nature, are subject to a statute of repose. Nat’l Property Investors, VIII v. Shell Oil Co., 950 F. Supp. 710, 713 (E.D.N.C. 1996); Colony Hill Condo. I Ass’n v. Colony Co., 320 S.E.2d 273 (N.C. Ct. App. 1984). The plaintiff’s knowledge of an alleged injury is not

relevant for the purposes of the statute of repose:

Unlike an ordinary statute of limitations which begins running upon accrual of the claim . . . the period contained in the statute of repose begins when a specific event occurs, regardless of whether a cause of action has accrued or whether any injury has resulted. . . . Thus, the repose serves as an unyielding and absolute barrier that prevents a plaintiff's right of action even before his cause of action may accrue, which is generally recognized as the point in time when the elements necessary for a legal wrong coalesce.

Black v. Littlejohn, 325 S.E.2d 469, 474–75 (N.C. 1985) (citations omitted); see also Bryant v. Don Galloway Homes, Inc., 556 S.E.2d 597, 600 (N.C. Ct. App. 2001) (noting that a statute of repose begins to run when the statutory triggering event occurs, “regardless of whether or not there has been an injury”). Moreover, “[w]hile equitable doctrines may toll statutes of limitation, they do not toll substantive rights created by statutes of repose.” Monson v. Paramount Homes, Inc., 515 S.E.2d 445, 449 (N.C. Ct. App. 1999).

In product liability actions, the statute of repose begins to run on “the date of initial purchase for use or consumption.” N.C. GEN. STAT. § 1-46.1(1). Before 2009, North Carolina law provided that no personal injury claims “based upon or arising out of any alleged defect or any failure in relation to a product shall be brought more than six years after the date of initial purchase for use or consumption.” N.C. GEN. STAT. § 1-50(a)(6) (1995). On October 1, 2009, the North Carolina legislature repealed N.C. GEN. STAT. § 1-50(a)(6) and enacted a new, twelve-year statute of repose. See N.C. GEN. STAT. § 1-46.1(1). However, this new statute applies only “to causes of action that accrue on or after” the effective date of the statute, October 1, 2009. See 2009 N.C. Sess. Laws 2009-420 § 3.

As such, courts applying North Carolina law have consistently applied N.C. GEN. STAT. § 1-50(a)(6)’s six-year statute of repose in cases where the product in question was first purchased or delivered, as here, before October 1, 2009. See, e.g., Robinson v. Bridgestone/Firestone N.

Am. Tire, LLC, 703 S.E.2d 883, 886–87 (N.C. Ct. App. 2011) (applying six-year statute of repose in product liability action involving allegedly defective tires purchased in 1995 or 1996, and declining to apply N.C. GEN. STAT. § 1-46.1(1)); Lackey v. DePuy Orthopaedics, Inc., No. 5:10cv30, 2011 WL 2791264, at \*3 (W.D.N.C. July 14, 2011) (holding that “the applicable statute of repose is N.C. GEN. STAT. § 150(a)(6), which was in effect at the time Plaintiff purchased the allegedly defective product”); Ferro v. Vol Vo Penta of the Americas, LLC, No. 5:17cv194, 2017 WL 3710071, at \*3 (E.D.N.C. Aug. 28, 2017) (finding that plaintiff’s claims involving products purchased before October 1, 2009, were governed by six-year statute of repose, while claims involving products purchased after that date were governed by twelve-year statute of repose); In re: Elk Cross Timbers Decking Mktg., No. 15cv18, 2015 WL 6467730, at \*11 (D.N.J. Oct. 26, 2015) (applying North Carolina law) (“Plaintiff Shepherd alleges that he ‘purchased and installed Decking on his home in 2007.’ (OAC ¶ 32.) Therefore, § 1-50(a)(6), the statute in effect at the time of his purchase, applies.”).

The Court finds that Plaintiff’s claims are governed by the six-year statute of repose in N.C. GEN. STAT. § 1-50(a)(6), because the latest date on which her TVT-O could have been purchased for use or consumption was the date of her implantation surgery, April 2, 2007, two years before the effective date of N.C. GEN. STAT. § 1-46.1(1). See In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig., 4:08-MD-2004, 2016 WL 873854, at \*3 (M.D. Ga. Mar. 4, 2016) (applying North Carolina law) (finding that N.C. GEN. STAT. § 1-50(a)(6) applied to plaintiff’s claims involving pelvic mesh device implanted in 2005). However, even applying N.C. GEN. STAT. § 1-46.1(1)’s twelve-year statute of repose, Plaintiff’s claims are barred as a matter of law. Plaintiff was implanted with the TVT-O on April 2, 2007, but she did not file suit until April 20, 2020, more than thirteen years later. Accordingly, Plaintiff’s claims were

extinguished by the statute of repose before she filed suit, and the Complaint must be dismissed with prejudice.

In response to the motion to dismiss, Plaintiff argues that a “disease exception” to the statute of repose applies to her claims and renders this lawsuit timely. However, this exception does not apply under the facts alleged in the Amended Complaint because Plaintiff does not allege that she suffers from a disease within the meaning of the exception. The “disease exception” to the statute of repose was first recognized in Wilder v. Amatex Corp., 336 S.E.2d 66 (N.C. 1985), a case involving a plaintiff who had developed asbestosis as a result of his prolonged exposure to the defendant’s chemicals. At issue in Wilder was whether the plaintiff’s personal injury claims were barred by N.C. GEN. STAT. ANN. § 1-15(b), which imposed a 10-year statute of repose for latent personal injury claims. Id. at 69. After reviewing the state of the law at the time the statute was enacted and the statute’s legislative history, which revealed that the term “disease” had been deliberately removed during the legislative process, the Wilder Court concluded that the statute of repose was not intended to apply to claims arising out of a latent disease that manifests itself over a long period of time. Id. at 72–73. The Court explained that such “[a] disease presents an intrinsically different kind of claim” than a “situation[] in which it was possible to identify a single point in time when plaintiff was first injured”:

Diseases such as asbestosis, silicosis, and chronic obstructive lung disease normally develop over long periods of time after multiple exposures to offending substances which are thought to be causative agents. It is impossible to identify any particular exposure as the “first injury.” Indeed, one or even multiple exposures to an offending substance in these kinds of diseases may not constitute an injury. The first identifiable injury occurs when the disease is diagnosed as such, and at that time it is no longer latent.

Id. at 71. The Fourth Circuit has followed the reasoning of Wilder to apply a latent disease exception to N.C. GEN. STAT. ANN. § 1-50(a)(6). See Hyer v. Pittsburgh Corning Corp., 790



F.2d 30, 33–34 (4th Cir. 1986).

Here, Plaintiff’s alleged urinary tract and bladder infections do not fit Wilder’s definition of a disease for purposes of the statute of repose. A true latent disease, such as the asbestosis at issue in Wilder, or the plaintiff’s leukemia associated with exposure to toxic discharges over many years in Stahle v. CTS Corp., 817 F.3d 96, 98 (4th Cir. 2016), develops within the body over an extended time period before manifesting any symptoms. Consequently, it is difficult, if not impossible, to determine the first point at which the plaintiff was first “injured.” Here, on the other hand, Plaintiff’s alleged urinary tract and bladder infections are discrete medical events that occurred at readily identifiable points in time. Because Plaintiff can pinpoint the times at which she was “injured” by a urinary tract or bladder infection, those injuries do not qualify as a latent disease. See Douglas v. Sandoz Pharms. Corp., No. 1:98cv911, 2000 WL 33342286, at \*5 (M.D.N.C. July 18, 2000) (finding that the plaintiff’s stroke was not a “disease” because the point at which she suffered the stroke was readily identifiable, even if the exact series of events leading up to the stroke could not be easily established).

Additionally, the Wilder Court reasoned that diseases, unlike other injuries, typically develop after multiple exposures to a harmful substance and that one particular exposure cannot be identified as the “injury-causing” event. Wilder, 336 S.E.2d at 70. Plaintiff’s alleged urinary tract and bladder infections do not fit within this narrow category of latent diseases. Taking the allegations of the Amended Complaint as true, all of Plaintiff’s alleged injuries are attributable to a single event: Plaintiff’s implantation with the TVT-O. As such, the Wilder Court’s reasons for distinguishing latent diseases from other injuries in the statute-of-repose context do not apply.

Finally, the categories of injuries alleged in the Amended Complaint go well beyond the Wilder Court’s narrow definition of “disease” and make clear that this is not a disease case. In

Paragraph 25 of the Amended Complaint, Plaintiff alleges that, as a result of her implantation with the TVT-O, she has suffered “significant mental and physical pain and suffering, has sustained permanent injury and permanent and substantial physical deformity and has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.” (Doc. No. 13, ¶ 23). In Paragraph 37, she alleges a laundry list of potential complications allegedly attributable to TVT-O, including mesh contraction, scar tissue formation, dyspareunia (pain with sexual intercourse), pelvic pain, nerve damage and pain, pelvic organ prolapse, and the need for additional corrective surgeries. (Id. at ¶ 35). Plaintiff’s allegations clearly focus on the bodily injuries she allegedly has sustained and do not mention any actual “disease.”

Another federal district court applying North Carolina law has addressed similar factual allegations and rejected the contention that the disease exception should apply in a case involving an implantable pelvic mesh device. In In re Mentor Corp., No. 4:13cv301, 2016 WL 4385846, at \*2 (M.D. Ga. Aug. 15, 2016), a multi-district litigation case involving a pelvic device called the “Obtape Transobturator Tape,” the plaintiff argued that North Carolina’s statute of repose did not bar her product liability claims arising out of her implantation with the defendant’s pelvic mesh device because her case qualified as a “disease case.” Reviewing the Fourth Circuit’s decisions addressing North Carolina’s statute of repose as interpreted by the North Carolina Supreme Court in Wilder, the federal district court for the Middle District of Georgia found that “cases fall within the ‘disease exception’ if (1) the plaintiff’s injury is a disease, (2) it is difficult to establish the exact time of injury (when the disease process started) and (3) it is difficult to establish that the disease was caused by the product.” Id.

Following the Fourth Circuit’s interpretation of Wilder, the In re Mentor Corp. court

determined that the disease exception in the North Carolina repose statute does not apply “in situations where it is possible to identify a single point in time when the plaintiff was first injured.” Id. at \*2. Because the plaintiff’s complications were directly attributable to the defendant’s pelvic mesh device and the plaintiff could not point to any evidence that she was diagnosed with a disease caused by the device, the In re Mentor Corp. court concluded that the disease exception did not apply. Id. at \*3 (explaining that the plaintiff “experienced symptoms when her medical device eroded through her bodily tissues. And while pelvic inflammatory disease can occur due to a variety of reasons other than an intrauterine device, the types of complications [the plaintiff] suffered—like erosion of her ObTape—were directly attributable to ObTape when they happened. Thus, the rationale behind the disease exception does not apply here.”); see also In re Mentor Corp. Obtape Transobturator Sling Prods. Liab. Litig., No. 4:12cv335, 2016 WL 873854, at \*2 (M.D. Ga. Mar. 4, 2016) (finding that the disease exception did not apply and reasoning, “Mrs. Wallace's claim is not a claim arising from disease that developed over many years after multiple exposures to a toxic substance; it is a claim arising from complications she contends were caused by a medical device that was implanted in her body”).

Here, similar to the plaintiff in In re Mentor Corp., Plaintiff seeks damages for personal injuries that she attributes to a specific event, the implantation of a pelvic mesh device, and nowhere in the Amended Complaint does she allege that she developed a latent disease as a result of her implantation with the mesh. Because she filed her Complaint more than 13 years after her implantation, her claims are barred under either the 6-year or 12-year version of North

Carolina's statute of repose, and the Complaint will be dismissed with prejudice.<sup>1</sup>

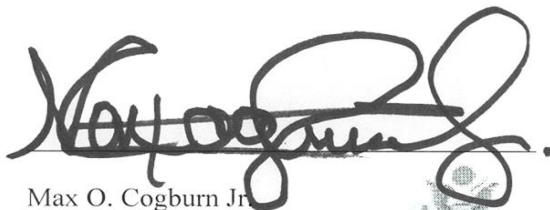
#### IV. CONCLUSION

For the reasons set forth above, this action is dismissed with prejudice.

**IT IS THEREFORE ORDERED** that:

- (1) Defendants' Motion to Dismiss, (Doc. No. 8), is **TERMINATED** as moot.
- (2) Defendants' Motion to Dismiss, (Doc. No. 14), is **GRANTED**.
- (3) This action is dismissed with prejudice.

Signed: January 25, 2021



Max O. Cogburn Jr.  
United States District Judge

---

<sup>11</sup> Because the statute of repose bars Plaintiff's claims, the Court does not address Defendants' alternative ground for dismissal.